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Docket No. 1177-001 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	
	:	
FRANK D. MARCUM	:	
	:	GAU 1614
Serial No.: 10/686,918	:	
	:	Examiner Unknown
Filed: October 16, 2003	:	
	:	

For: COMPOSITION AND METHOD FOR TREATMENT AND PREVENTION OF TRAUMATIC SYNOVITIS AND DAMAGE TO ARTICULAR CARTILAGE

PETITION TO MAKE SPECIAL PURSUANT TO 37 C.F.R. § 1.102(d) AND M.P.E.P. § 708.02

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.102(d) and M.P.E.P. § 708.02 I & II Applicant hereby respectfully files this "Petition to Make Special" for the above-styled application. Pursuant to 37 C.F.R. § 1.102(d) and M.P.E.P. § 708.02 (A), the Commissioner is hereby authorized to debt Deposit Account Number 19-4430 for the $130.00 petition fee pursuant to 37 C.F.R. § 1.17(h). A fee sheet authorizing the Commissioner to debt the referenced deposit account is submitted herewith.

In the above-styled application, a set of claims is pending in which Applicant believes is directed to a single invention. However, in accordance with M.P.E.P. § 708.02 VIII (B), should the Office determine that an election/restriction requirement is necessary, the

Applicant is willing to comply with the established telephone restriction practice.

Pursuant to M.P.E.P. § 708.02 (C), a copy of the International Search Report issued from the ISA/US and mailed on August 6, 2004, for the corresponding PCT Application No. PCT/US03/32555 (International Publication Number WO 2004/034980 A3) is being submitted concurrently herewith as Exhibit 4 to the Declaration in support of this Petition to Make Special executed by the applicant/inventor which is attached to this Petition as Exhibit A. In addition, pursuant to a conversation with the Examiner, Mr. Everett White, on October 26, 2004, the submission of the International Search Report is believed to satisfy the requirements of M.P.E.P. § 708.02(C). However, in the abundance of caution, Applicant submits herewith an Information Disclosure Statement (IDS) (attached to this Petition as Exhibit B) which includes: 1) the reference cited in the International Search Report; 2) certain references cited in the background of the above-styled application; 3)certain references cited in the background of the reference cited by the Examiner; and 4) references that were otherwise known to Applicant. These references are deemed to be the most closely related references to the subject matter encompassed by the claims that are known to Applicant and are submitted in accordance with M.P.E.P. § 708.02 VIII (D) and 37 C.F.R. § 1.56. A detailed discussion of the references which points out how the claimed subject matter is patentable over the references is submitted with the IDS pursuant to M.P.E.P. § 708.02 VIII (E). Consideration of these references and making the same of record in the instant application is respectfully requested.

In Addition, attached hereto as Exhibit C is a "Preliminary Amendment" which is being submitted to correct inadverdent typographical errors in the specification and also to more distinctly and clearly set forth Applicant's claimed invention, in particular, to clarify that certain of the compositions of the invention are specially formulated for intra-articular or other parenteral use. The amendment to the claims, as set forth in the Preliminary Amendment (Exhibit C), is believed to clearly and distinctly claim Applicant's patentable invention and distinguish over the art of record without question, thereby placing the application in condition for allowance.

Applicant respectfully files this Petition to Make Special and requests a grant of expedited review for the above-styled application pursuant to M.P.E.P. §§ 708.02 I & II . In particular, the above-styled invention is actively being infringed upon under M.P.E.P. § 708.02 II and Applicant has identified prospective manufacturers for the invention, with sufficient capital that will not manufacture the new drug compositions in quantity for FDA approval unless certain that the patent will issue under M.P.E.P. § 708.02 I.

The Declaration (Exhibit A)

The Declaration In Support of this Petition to Make Special executed by the Applicant/Inventor, Dr. Frank Marcum, (attached hereto as Exhibit A) clearly establishes proper grounds for expedited review under M.P.E.P. §§ 708.02 I & II. In particular, the Declaration establishes that there is an infringing device or product, namely a composition, actually on the market, which infringes one or more of the claims of the above-styled

application. The Applicant has made a rigid comparison of the alleged infringing product (composition) and in his opinion, some of the claims of the above-styled application are unquestionably infringed.

In particular, attached to the Declaration as Exhibit 1 are three sequential black and white photographs showing a vial of Applicant's composition with the label affixed thereto. Applicant's composition is currently being compounded on an as needed basis pursuant to a valid prescription by Cornerstone Pharmacy & Compounding Laboratory. The prescription number, R004868 and Applicant's name, Frank Marcum D.V.M., as the prescribing veterinarian, are clearly visible on the label shown of the specimen of Applicant's composition. The listed ingredients of Applicant's composition are clearly visible, namely, N-Acetyl-D Gulcosamine, Chondroitin Sulfate and Hyalyuronate Acid. The vial is also clearly marked "Patent Pending."

Attached to the Declaration as Exhibit 2 are three sequential black and white photographs showing a vial of the infringing composition and the label affixed thereto. The infringing composition is produced by Wedgewood Pharmacy and the label clearly indicates that the listed ingredients of the infringing composition are the same as for Applicant's composition, namely N-Acetyl-D Gulcosamine, Chondroitin and Hyalyuronic Acid. Attached as Exhibit 3 to the Declaration are color photographs of Applicant's composition and of the infringing composition. Thus, the infringing composition clearly has the same ingredients as Applicant's composition and infringes one or more claims of Applicant's

patent application and is believed to satisfy the infringement requirements of M.P.E.P. § 708.02 II. A grant of this petition is, therefore, respectfully requested.

Pursuant to M.P.E.P. § 708.02 I, Applicant has identified prospective manufacturers for his products produced in accordance with the invention. In particular, in the Declaration Applicant states that his composition is currently being sold as a compounded product on a prescription by prescription basis and is not currently being manufactured in quantity. Applicant has identified ArthroDynamic Technologies, LLC, a Kentucky corporation, as prospective manufacturer of certain of the compositions embodied by the above-styled application, namely for compositions suitable for use as a medical device manufactured in accordance with FDA requirements and Good Manufacturing Practices (GMP). The prospective manufacturer possesses sufficient capital and facilities, or access to facilities on a contract basis, which will be made available if a patent is granted. The prospective manufacturer is not obligated to manufacture the medical device composition in quantity unless certain the patent will be granted on the above-styled application. The prospective manufacturer has obligated itself to manufacture the invention in the United States or its possessions, in quantity immediately upon the allowance of claims or issuance of a patent which will protect the investment of capital and facilities. Thus, Applicant's identification of a prospective manufacturer for the medical device compositions is believed to satisfy the manufacturer requirements of M.P.E.P. § 708.02 I and a grant of this petition is respectfully requested.

In addition, as stated by the Applicant in his Declaration, ArthroDynamic Technologies, LLC in conjunction with Bioniche Life Sciences, Inc, a Canadian Corporation with subsidiary corporations in the United States, have been identified as prospective manufacturers of certain compositions embodied in the above-styled application that are intended for use as drugs for human and animal use. These drug formulations will require FDA approval and, therefore, require an investment of significant capital and other resources. The prospective manufacturers possess sufficient capital and facilities, or access to facilities on a contract basis, which will be made available if a patent is granted. The prospective manufacturers will not manufacture the new drug compositions for FDA approval unless certain the patent will be granted on the above-styled application. The prospective manufacturers have obligated themselves to manufacture the invention in the United States or its possessions, in quantity sufficient for FDA approval immediately upon the allowance of claims or issuance of a patent which will protect the investment of capital and facilities. Thus, Applicant's identification of a prospective manufacturers for the human and animal drug compositions of the invention is believed to satisfy the manufacturer requirements of M.P.E.P. § 708.02 I and a grant of this petition is respectfully requested.

Related Matters

No additional fee is believed to be due at this time, however, the Commissioner is hereby authorized to debit Deposit Account Number 19-4430 for any additional fees deemed to be due or issue a credit for any overpayment thereof. The Examiner is encouraged to

contact the undersigned attorney directly if such contact will enhance the granting of this Petition to Make Special and otherwise enhance the efficient prosecution of the application to issue.

Respectfully submitted,
STOCKWELL & ASSOCIATES, PLLC

J.W. Seanor, D.V.M.
Registration No. 40,804

247 North Broadway
Lexington, KY 40507
(859) 223-3400

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as Regular Mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450,

November 2, 2004
Date

By

PTO/SB/17 (10-04v2)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 130.00

Complete if Known	
Application Number	10/686,918
Filing Date	October 16, 2004
First Named Inventor	Marcum, Frank D.
Examiner Name	Everett White
Art Unit	1623
Attorney Docket No.	1177-001

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 19-4430

Deposit Account Name: Stockwell & Associates

The Director is authorized to: *(check all that apply)*

☑ Charge fee(s) indicated below ☐ Credit any overpayments

☐ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	790	2001	395	Utility filing fee	
1002	350	2002	175	Design filing fee	
1003	550	2003	275	Plant filing fee	
1004	790	2004	395	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below	Fee Paid
Total Claims		-20** =		X	=
Independent Claims		- 3** =		X	=
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	88	2201	44	Independent claims in excess of 3
1203	300	2203	150	Multiple dependent claim, if not paid
1204	88	2204	44	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,370	2453	685	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	130.00
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 130.00

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	J.W. (Bill) Seaner, DVM, JD	*Registration No. (Attorney/Agent)*	40,804	*Telephone*	859-223-3400
Signature	J.W. Seaner DVM			*Date*	November 2, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

EXHIBIT A TO PETITION

Docket No. 1177-001 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	
	:	
FRANK D. MARCUM	:	
	:	GAU 1614
Serial No.: 10/686,918	:	
	:	Examiner Unknown
Filed: October 16, 2003	:	
	:	

For: COMPOSITION AND METHOD FOR TREATMENT AND PREVENTION OF TRAUMATIC SYNOVITIS AND DAMAGE TO ARTICULAR CARTILAGE

DECLARATION UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITIONTO MAKE SPECIAL PURSUANT TO 37 C.F.R. § 1.102 & M.P.E.P. § 708.02

I **FRANK D. MARCUM** declare as follows:

1. I make this affidavit from my own personal knowledge.

2. All Statements made herein are made based upon my own personal knowledge and are true.

3. I am the inventor of the above-styled patent application.

Infringement Under M.P.E.P. § 708.02 II

4. There is an infringing device or product, namely a composition, actually on the market, which infringes one or more of the claims of the above-styled application.

5. A rigid comparison of the alleged infringing composition has been made by me and, in my opinion, some of the claims of the above-styled application are unquestionably

infringed.

6. Attached hereto as Exhibit 1 are three sequential black and white photographs showing a vial of my composition and the label affixed thereto. My composition is currently being compounded on an as needed basis pursuant to a valid prescription by Cornerstone Pharmacy & Compounding Laboratory. The prescription number, ℞004868 and my name, Frank Marcum D.V.M., as the prescribing veterinarian, are clearly visible on the label shown of the specimen of my composition. The composition is compounded under the trade name POLYGLYCAN™ Which is also clearly visible on the label. The listed ingredients of the composition are clearly visible, namely, N-Acetyl-D Gulcosamine, Chondroitin Sulfate and Hyalyuronate Acid. The vial is also clearly marked "Patent Pending."

7. Attached hereto as Exhibit 2 are three sequential black and white photographs showing a vial of the infringing composition and the label affixed thereto. The infringing composition is produced by Wedgewood Pharmacy and the label clearly indicates that the listed ingredients of the infringing composition are the same as for my composition, namely N-Acetyl-D Gulcosamine, Chondroitin and Hyalyuronic Acid.

8. Attached hereto as Exhibit 3 are color photographs of my composition and of the infringing composition. As set forth in paragraph 7 above, the infringing composition

clearly has the same ingredients as my composition and infringes one or more claims of my patent application.

Manufacture Under M.P.E.P. § 708.02 I

9. My composition is currently being sold as a compounded product on a prescription by prescription basis and is not currently being manufactured in quantity. ArthroDynamic Technologies, LLC, a Kentucky corporation, has been identified as prospective manufacturer of certain of the compositions embodied by the above-styled application, namely as a medical device manufactured in accordance with FDA requirements and Good Manufacturing Practices (GMP). The prospective manufacturer possesses sufficient capital and facilities, or access to facilities on a contract basis, which will be made available if a patent is granted. The prospective manufacturer is not obligated to manufacture the medical device composition in quantity unless certain the patent will be granted on the above-styled application. The prospective manufacturer has obligated itself to manufacture the invention in the United States or its possessions, in quantity immediately upon the allowance of claims or issuance of a patent which will protect the investment of capital and facilities.

10. Likewise, ArthroDynamic Technologies, LLC in conjunction with Bioniche Life Sciences, Inc, a Canadian Corporation with subsidiary corporations in the United States, have been identified as prospective manufacturers of certain compositions

embodied in the above-styled application that are intended for use as drugs for human and animal use. These drug formulations will require FDA approval and, therefore, require an investment of significant capital and other resources. The prospective manufacturers possess sufficient capital and facilities, or access to facilities on a contract basis, which will be made available if a patent is granted. The prospective manufacturers will not manufacture the new drug compositions for FDA approval unless certain the patent will be granted on the above-styled application. The prospective manufacturers have obligated themselves to manufacture the invention in the United States or its possessions, in quantity sufficient for FDA approval immediately upon the allowance of claims or issuance of a patent which will protect the investment of capital and facilities.

PCT - International Search Report Under M.P.E.P. § 708.02 VIII (C)

11. Submitted herewith as Exhibit 4 is a copy of the International Search Report issued from the ISA/US and mailed on August 6, 2004, for my corresponding PCT Application No. PCT/US03/32555 (International Publication Number WO 2004/034980 A3). The International Search Report searched U.S Classes 514/53, 62 and cites one reference, a published U.S. Patent Application to Hammerly (Publication No. US 2001/0046971) published on November 29, 2001. For the reasons set forth in the accompanying "Petition to Make Special" and Information Disclosure Statement (IDS), it is my belief that the above-

styled application and invention is distinguishable over the Hammerly reference and is non-obvious and that my invention is patentable.

12. I have a good knowledge of the pertinent prior art, including the art cited in the International Search Report and IDS referenced in paragraph 11 above and I believe the subject matter of the above-styled application is patentable.

Summary

13. Therefore, because: 1) my invention is actively being infringed upon; and 2) because I have identified prospective manufacturers for the invention, with sufficient capital that will not manufacture unless certain that the patent will issue, I respectfully request a grant of the Petition to Make Special and grant expedited review of the above-styled application.

14. I understand and acknowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statement may jeopardize the validity of the application or any patent issuing therefrom.

FRANK D. MARCUM

NOV. 2, 2004
Date

EXHIBIT 1

APPLICANT:

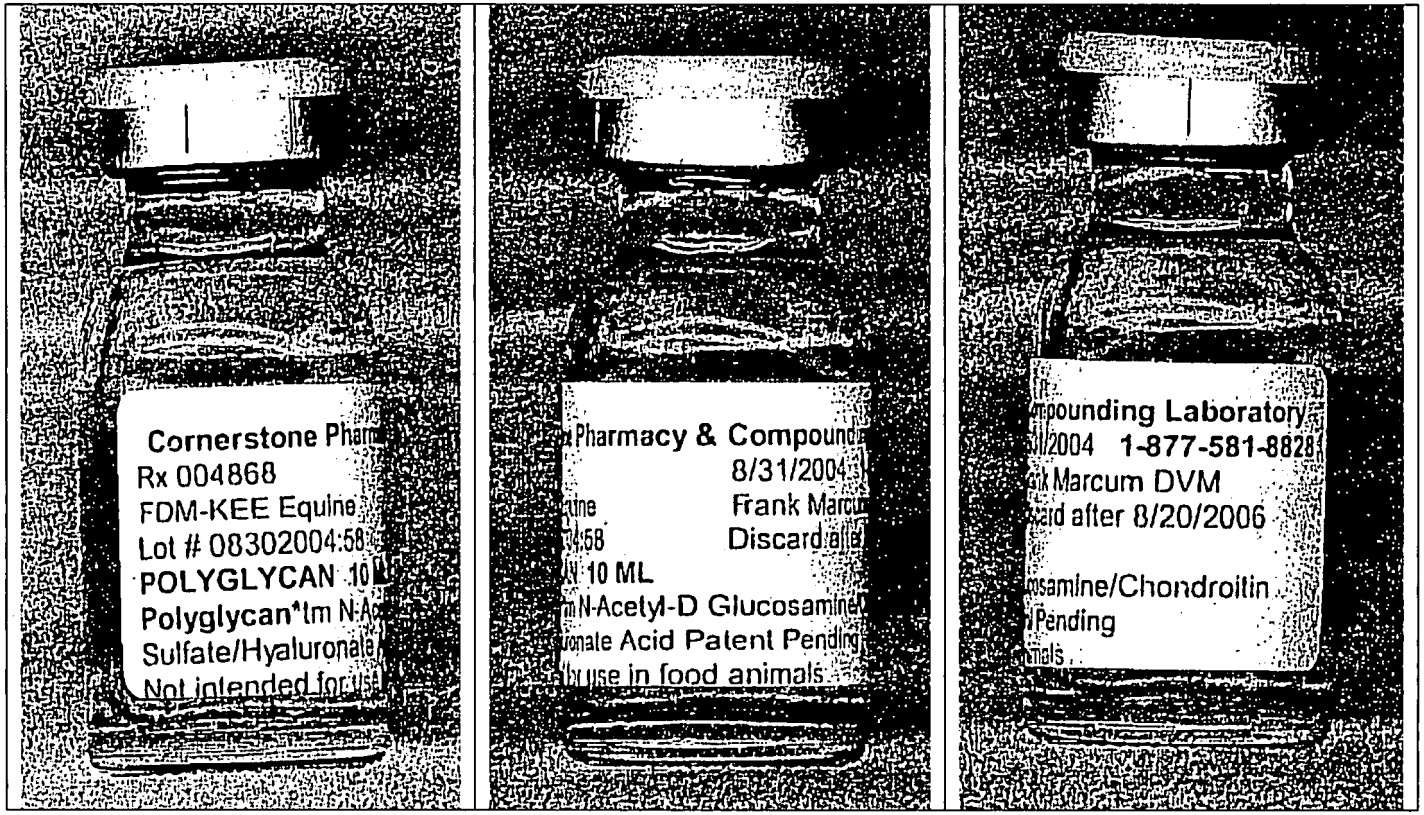
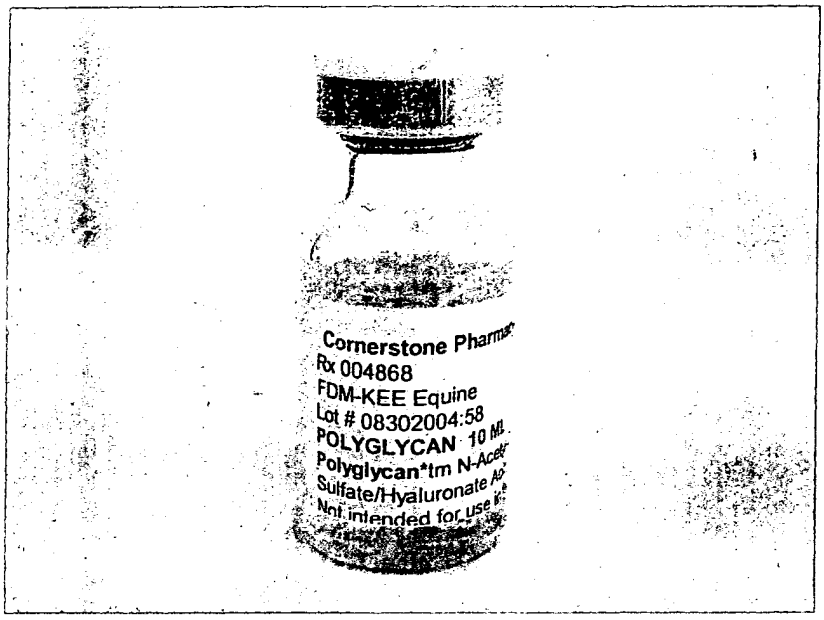
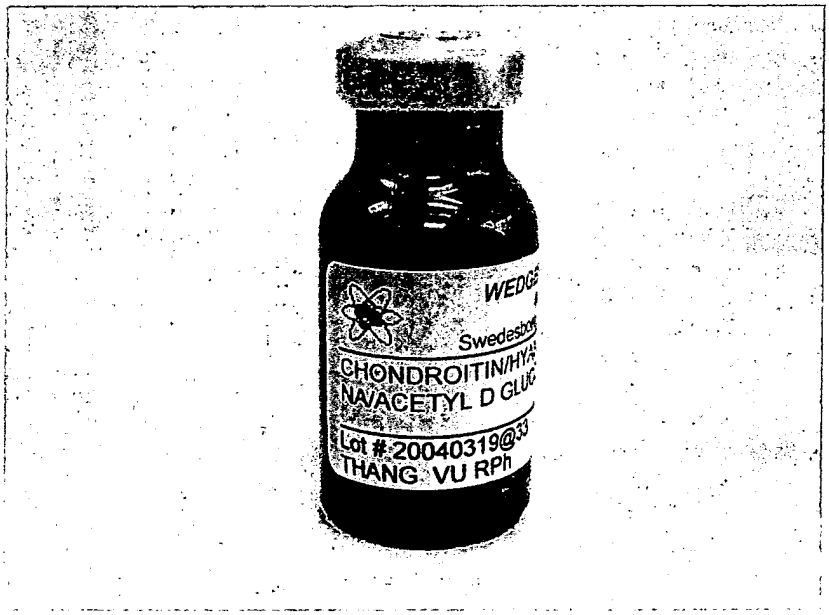


EXHIBIT 2

INFRINGER:

EXHIBIT 3


Cornerstone Pharm
Rx 004868
FDM-KEE Equine
Lot # 08302004:58
POLYGLYCAN 10 Ml
Polyglycan*tm N-Acet
Sulfate/Hyaluronate
Not intended for use


WEDG
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Lot # 20040319@33
THANG VU RPh

EXHIBIT 4

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
J.W. SEANSOR
STOCKWELL & ASSOCIATES
861 CORPORATE DRIVE
SUITE 201
LEXINGTON, KY 40503

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

	Date of Mailing (*day/month/year*) 06 AUG 2004
Applicant's or agent's file reference 1177-001 PCT	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US03/32555	International filing date (*day/month/year*) 16 October 2003 (16.10.2003)
Applicant MARCUM, FRANK D.	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34, chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

   Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 *bis*.1 and 90 *bis*.3, respectively, before the completion of the technical preparations for international publication.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer EVERETT WHITE Telephone No. (703)308-1235

Form PCT/ISA/220 (April 2002) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 1177-001 PCT	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US03/32555	International filing date (*day/month/year*) 16 October 2003 (16.10.2003)	(Earliest) Priority Date (*day/month/year*) 16 July 2002 (16.07.2002)
Applicant MARCUM, FRANK D.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:
   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
2. ☐ **Certain claims were found unsearchable** (See Box I).
3. ☐ **Unity of invention is lacking** (See Box II).
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is Figure No. ____
   ☐ as suggested by the applicant.
   ☐ because the applicant failed to suggest a figure.
   ☐ because this figure better characterizes the invention.
   ☐ None of the figures

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/32555

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61K 31/715, 31/70
US CL : 514/53, 62
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 514/53, 62

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2001/0046971 A1 (HAMMERLY) 29 November 2001 (29.11.2001), see entire document.	1-36

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
20 March 2004 (20.03.2004)

Date of mailing of the international search report
06 AUG 2004

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Form PCT/ISA/210 (second sheet) (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.